

REPLACED BY
PART 34 AMPL

CLAIMS

1. A method for preparing a sterile composition of a pharmaceutical compound comprising combining solvent with a non-sterile pharmaceutical compound to yield a sterile pharmaceutical compound, optionally removing all or part of the solvent, and under sterile conditions combining the compound with a pharmaceutically acceptable carrier.
2. A method according to Claim 1 wherein the non-sterile pharmaceutical compound is a powder.
3. A method according to Claim 2 wherein the powder is a micronized powder.
4. A method according to any of Claims 1 to 3 wherein the compound is a steroid.
5. A method according to Claim 4 wherein the compound is budesonide or fluticasone.
6. A method according to any of Claims 1 to 5 wherein the solvent comprises an alcohol.
7. A method according to any of Claims 1 to 5 wherein the solvent comprises a Class 3 solvent.
8. A method according to any of Claims 1 to 5 wherein the solvent comprises a Class 2 solvent.
9. A method according to any of Claims 1 to 8, comprising combining solvent with the compound at an elevated temperature, suitably from 20°C below the boiling point of the solvent up to its boiling point.
10. A method according to Claim 9 wherein the solvent is at reflux.

11. A method according to any of Claims 1 to 8 wherein the solvent is at 30-50°C.
12. A method according to any of Claims 1 to 11, comprising using sufficient solvent to obtain a slurry of the compound.
13. A method according to any of Claims 1 to 12, comprising removing solvent under reduced pressure.
14. A method according to any of Claims 1 to 12 comprising removing solvent at atmospheric pressure.
15. A method according to any of Claims 1 to 14, comprising removing solvent to yield an essentially solvent-free powder.
16. A method according to any of Claims 1 to 15, comprising using sufficient solvent to obtain a solution of the compound.
17. A method according to Claim 16 comprising filtering the solution.
18. A method according to Claim 17 using a filter having a pore size of 0.2 μ m or less.
19. A method according to any of Claims 1 to 18, comprising combining the sterile pharmaceutical compound with water to form a suspension.
20. A method according to Claim 19, wherein the water contains surfactant.
21. A method according to Claim 19 or 20, comprising removing solvent from the suspension.
22. A method according to Claim 21, wherein solvent is removed under reduced

pressure.

23. A method according to Claim 21, wherein solvent is removed at atmospheric pressure.
24. A method according to any of Claims 19 to 23, comprising treating the suspension to obtain a particle size distribution having a mass median diameter less than 10 μ m.
25. A method according to Claim 24, comprising treating the suspension to obtain a particle size distribution having a mass median diameter in the range 1-5 μ m.
26. A method according to Claim 24, comprising treating the suspension to obtain a particle size distribution having a mass median diameter in the range 2-3 μ m.
27. A method according to any of Claims 24 to 26, comprising storing the sterile composition in sterile containers.
28. A method according to Claim 27, comprising storing the sterile composition in sterile ampoules.
29. A method for preparing a sterile composition of a pharmaceutical compound comprising combining solvent with a non-sterile pharmaceutical compound so as to form a solution and filtering the solution to yield a sterile solution of the pharmaceutical compound.
30. A method according to Claim 29 wherein the non-sterile pharmaceutical compound is a powder.
31. A method according to Claim 30 wherein the powder is a micronized powder.
32. A method according to any of Claims 29 to 31 wherein the compound is a

steroid.

33. A method according to Claim 32 wherein the compound is budesonide or fluticasone.
34. A method according to any of Claims 29 to 33 wherein the solvent comprises an alcohol.
35. A method according to any of Claims 29 to 33 wherein the solvent comprises a Class 3 solvent.
36. A method according to any of Claims 29 to 33 wherein the solvent comprises a Class 2 solvent.
37. A method according to any of Claims 29 to 36, comprising combining solvent with the compound at an elevated temperature, suitably from 20°C below the boiling point of the solvent up to its boiling point.
38. A method according to Claim 37 wherein the solvent is at reflux.
39. A method according to any of Claims 29 to 36 wherein the solvent is at 30-50°C.
40. A method according to any of Claims 29 to 39, comprising removing solvent from the sterile solution under reduced pressure.
41. A method according to any of Claims 29 to 39 comprising removing solvent from the sterile solution at atmospheric pressure.
42. A method according to any of Claims 29 to 41, comprising removing solvent from the sterile solution to yield a solvent-free powder.
43. A method according to Claim 42 using a filter having a pore size of 0.2µm or

less.

44. A method according to any of Claims 29 to 43 comprising combining the sterile solution of the pharmaceutical compound with water to form a suspension.
45. A method according to Claim 44, wherein the water contains surfactant.
46. A method according to Claim 44 or 45, comprising removing solvent from the suspension.
47. A method according to Claim 46, wherein solvent is removed under reduced pressure.
48. A method according to Claim 46, wherein solvent is removed at atmospheric pressure.
49. A method according to any of Claims 44 to 48, comprising treating the suspension to obtain a particle size distribution having a mass median diameter less than 10 μ m.
50. A method according to Claim 49, comprising treating the suspension to obtain a particle size distribution having a mass median diameter in the range 1-5 μ m.
51. A method according to Claim 49, comprising treating the suspension to obtain a particle size distribution having a mass median diameter in the range 2-3 μ m.
52. A method according to any of Claims 49 to 51, comprising combining the sterile composition with a carrier.
53. A method according to any of Claims 49 to 52, comprising storing the sterile composition in sterile containers.

54. A method according to Claim 53, comprising storing the sterile composition in sterile ampoules.
55. A method for preparing a sterile composition of a pharmaceutical compound comprising combining solvent with a suspension of a non-sterile pharmaceutical compound to yield a sterile suspension of a pharmaceutical compound, removing solvent, and under sterile conditions combining the sterile suspension with a pharmaceutically acceptable carrier.
56. A method according to Claim 55, wherein the compound is a steroid.
57. A method according to Claims 55 or 56, wherein the solvent comprises an alcohol.
58. A method according to Claim 55 or 56, wherein the solvent comprises a Class 3 solvent.
59. A method according to Claim 55 or 56, wherein the solvent comprises a Class 2 solvent.
60. A method according to any of Claims 55 to 59, comprising combining solvent with the compound at an elevated temperature, suitably not less than 20°C below its boiling point.
61. A method according to any of Claims 55 to 59, wherein solvent is at 30-50°C.
62. A method according to any of Claims 55 to 61, comprising removing solvent under reduced pressure.
63. A method according to any of Claims 55 to 61, comprising removing solvent at atmospheric pressure.

64. A method according to any of Claims 55 to 63, wherein the suspension contains a surfactant.
65. A method according to any of Claims 55 to 64, comprising treating the suspension to obtain a particle size distribution having a mass median diameter less than 10 μ m.
66. A method according to Claim 65, comprising treating the suspension to obtain a particle size distribution having a mass median diameter in the range 1-5 μ m.
67. A method according to Claim 65, comprising treating the suspension to obtain a particle size distribution having a mass median diameter in the range 2-3 μ m.
68. A method according to any of Claims 65 to 67, comprising storing the sterile suspension in sterile containers.
69. A method according to Claim 68, comprising storing the sterile suspension in sterile ampoules.
70. A sterile composition prepared according to the method of any of Claims 1 to 69.
71. A sterile composition according to Claim 70 wherein the composition is a suspension.
72. A sterile powder prepared according to any of Claims 1 to 15.
73. A sterile powder prepared according to any of Claims 40 to 42.
74. Apparatus for preparing a sterile composition of a pharmaceutical compound, comprising a container defining a sterile inner compartment, a first vessel

containing a solvent, and a second vessel containing a non-sterile pharmaceutical compound, arranged so that the solvent can be combined with the non-sterile compound to yield a sterile compound within the compartment, the compartment also containing a sterile aqueous solution into which the sterile compound can be introduced to form a sterile suspension, optionally an apparatus for alteration of the particle size distribution of the suspension and further optionally a sterile exit line for transfer of sterile suspension to sterile containers.

75. Apparatus according to Claim 74, further comprising a sterile filter.
76. Apparatus according to Claim 75, wherein the sterile filter has a pore size of 0.2 μ m or less.